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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* DAVID TIEN-TUNG OU-YANG

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Appeal 2015-007106  
Application 12/397,760<sup>1</sup>  
Technology Center 1600

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Before ERIC B. GRIMES, RYAN H. FLAX and DAVID COTTA,  
*Administrative Patent Judges.*

COTTA, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an infusion therapy medical device, or a component of an infusion therapy medical device, that comprises a coating. The Examiner rejected the claims on appeal as unpatentable under 35 U.S.C. § 103(a) and on the grounds of non-statutory obviousness-type double patenting.

We affirm.

STATEMENT OF THE CASE

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<sup>1</sup> According to Appellants, the real party in interest is Becton Dickinson and Company. App. Br. 1.

Claims 1, 3, 5, 7, 9, 10, and 12–23 are on appeal. Claim 1 is illustrative and reads as follows (emphasis added):

1. An infusion therapy medical device or a component of an infusion therapy medical device that comprises a coating, comprising:

a liquid ultraviolet (UV) curable coating matrix comprising;

from 10% to 90% by weight an acrylate oligomer having two or more functional groups and selected from the group consisting of acrylated aliphatic urethanes, acrylated aromatic urethanes, acrylated polyesters, unsaturated polyesters, acrylated polyethers, and acrylated acrylics; and

from 5% to 90% by weight an acrylate monomer having two or more acrylated functional groups and selected from the group consisting of 2-ethyl hexyl acrylate, isooctyl acrylate, isobornylacrylate, 1,6-hexanediol diacrylate, diethylene glycol diacrylate, triethylene glycol diacrylate, pentaerythritol tetra acrylate, pentaerythritol tri acrylate, dimethoxy phenyl acetophenone hexyl methyl acrylate, and 1,6-hexanediol methacrylate;

from 1 to 10 parts by weight a photoinitiator, the photoinitiator selected from the group consisting of benzoin ethers, acetophenones, benzoyl oximes, acyl phosphine oxide, Michler's ketone, thioxanthone, anthroquinone, benzophenone, methyl diethanol amine, and 2-N-butoxyethyl-4-(dimethylamino) benzoate;

from 0.1 to 30 parts by weight a rheological modifier in 100 parts UV curable composition, the rheological modifier selected from the group consisting of organic clay, castor wax, polyamide wax, polyurethane, and fumed silica; and

from 0.5 to 50 parts by weight an antimicrobial agent in 100 parts UV curable composition, the antimicrobial agent selected from the group consisting of aldehydes, anilides, biguanides, bis-phenols, and quaternary ammonium compounds, and *excluding metal salts*, wherein the antimicrobial agent is configured to diffuse out of the cured matrix when the cured matrix is softened by a fluid, and wherein upon exposure to a UV source, the liquid UV curable coating matrix cures to form a

solid, clear, substantially colorless hydrophilic material that is capable of permanently coating an infusion therapy medical device or component.

The claims stand rejected as follows:

Claims 1, 3, 5, 7, 12–17, and 23 as unpatentable under 35 U.S.C. § 103(a) over the combination of Krongauz,<sup>2</sup> Elton,<sup>3</sup> and Ong.<sup>4</sup>

Claims 9, 10, and 18–22 as unpatentable under 35 U.S.C. § 103(a) over the combination of Krongauz, Elton, Ong, and Nishtala.<sup>5</sup>

Claims 1, 3, 7, 9, 10, and 12–23 were rejected on the ground of non-statutory obviousness-type double patenting over claims 1–19 of US Patent No. 8,691,887. Appellant does not address the Examiner’s double patenting rejection. We therefore summarily affirm the obviousness-type double patenting rejection. *See* Manual of Patent Examining Procedure § 1205.02 (“If a ground of rejection stated by the examiner is not addressed in the appellant’s brief, that ground of rejection will be summarily sustained by the Board.”).

#### REJECTION OF CLAIMS 1, 3, 5, 7, 12–17, AND 23 OVER THE COMBINATION OF KRONGAUZ, ELTON, AND ONG

Appellant argues claims 1, 3, 5, 7, 12–17, and 23 together as a group. We designate claim 1 as representative of the group.

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<sup>2</sup> Krongauz et al., US Patent Publication No. 2009/0324666 A1, published Dec. 31, 2009 (“Krongauz”).

<sup>3</sup> Elton, US Patent No. 5,077,352, issued Dec. 31, 1991 (“Elton”).

<sup>4</sup> Ong et al., US Patent Publication No. 2005/0080158 A1, published Apr. 14, 2005 (“Ong”).

<sup>5</sup> Nishtala et al., WO 2009/012336 A1, published Jan. 22, 2009 (“Nishtala”).

The Examiner found that Krongauz taught methods for making antimicrobial resins comprising all of the elements of claim 1 with the exception that it did not teach the inclusion of a rheological modifier such as fumed silica and did not teach the claimed antimicrobial compounds. Ans. 2–4. The Examiner found that Elton taught the missing element of using fumed silica gel as a rheological modifier and that Ong taught the claimed antimicrobial compounds. *Id.* at 4. The Examiner concluded:

[I]t would have been obvious to a person of ordinary skill in the art at the time of the instant invention to add fumed silica to the composition of Krongauz, and to substitute a biguanide or bisphenol antimicrobial for silver salts to form a material which is capable of permanently coating an infusion therapy medical device or component since Krongauz teaches a coating comprising monomers, oligomers, and photoinitiators that are essentially identical to the claimed ingredients, Elton teaches that fumed silica gel functions as a rheological modifier to obtain a composition with the desired thickness, and Ong teaches that biguanide or bisphenol compounds can substitute in the acrylate-urethane coating for the silver salts of Krongauz.

*Id.* at 4–5.

Appellant argues that Ong is not analogous art and thus does not qualify as prior art for purposes of an obviousness determination. App. Br. 9. “Whether a reference in the prior art is ‘analogous’ is a fact question.” *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992) (citing *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 n.9 (Fed. Cir. 1987)). “Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir.

2004). “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d at 659.

The problem addressed by Appellant was to provide an antimicrobial coating for medical devices. *See* Specification ¶ 13 (“there is a need for an effective antimicrobial coating that can be easily applied to medical devices constructed of polymeric materials and metals”). Ong addresses a similar problem, as reflected in the following discussion from Ong’s “Background of the Invention”:

What is needed is an antimicrobial agent that can be incorporated, or embedded, into a polymeric coating prior to polymerization, where that antimicrobial agent survives polymerization. In particular, what is needed is an antimicrobial agent incorporated into a polymeric coating that is applied to surfaces, and that is free from toxic effects and is durable over the lifespan of the polymer coating.

Ong ¶ 10. The solution disclosed by Ong is a radiation cured antimicrobial coating. *Id.* at Abstract. Ong’s antimicrobial agent is non-toxic (*id.* at ¶ 19), “migrates to the coated surface” and is “durable over the lifespan of the polymer coating.” *Id.* at ¶ 21. Ong’s coating is taught to be “suitable for coating flooring, furniture, cabinetry and other products that are susceptible to bacterial/microbial contamination” (*id.* at ¶ 22) and can be incorporated “on surfaces in health care and food service facilities where bacteria and bioburdens pose a health hazard.” *Id.* at ¶ 23.

Both Ong and Appellant sought to develop a durable, non-toxic anti-microbial coating. Given this similarity in purpose, the pertinence of the properties of Ong's antimicrobial agent, and Ong's teaching that its coating can be incorporated on surfaces in health care facilities, we find that Ong would have "commended itself" to an inventor considering the problem addressed by Appellant.

We acknowledge, but are not persuaded by, Appellant's contention that the present invention "addresses problems related to Catheter Related Blood Stream Infection (CRBSI)" (*see* App. Br. 10) because the Specification describes the problems addressed by Appellant more broadly, (*see* Specification ¶ 13), and discusses CRBSI only as an example of type of problem faced. *See id.* at ¶¶ 7 and 14. Moreover, the claims are not limited to CRBSI and Appellant has not provided persuasive evidence or argument to establish that the person of ordinary skill in the art would have found Ong inapplicable to CRBSI-related problems. *See Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989) ("Attorneys' argument is no substitute for evidence."); *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Accordingly, we affirm the Examiner's rejection of claim 1 over the combination of Krongauz, Elton, and Ong. Because they were not argued separately, claims 3, 5, 7, 12–17, and 23 fall with claim 1.

#### REJECTION OF CLAIMS 9, 10, AND 18–22 OVER THE COMBINATION OF KRONGAUZ, ELTON, ONG, AND NISHTALA

Claims 9, 10 and 18–22 require various antimicrobials that the Examiner found were not disclosed in Ong. The Examiner found that these antimicrobials were obvious in view of Nishtala, because Nishtala disclosed

that they were known equivalents of the antimicrobials disclosed in Ong.

The Examiner explained:

[I]t would have been obvious to a person of ordinary skill in the art at the time of the instant invention to substitute cetyl pyridinium chloride (claims 9 and 20), alexidine (claims 10 and 19), chlorhexidine diacetate (claim 21), or benzalkonium chloride (claim 22) for the antimicrobial taught in the combination of Krongauz, Elton, and Ong since Nishtala teaches that cetyl pyridinium chloride, alexidine (claims 10 and 19), chlorhexidine diacetate (claim 21), or benzalkonium chloride are known as equivalents which perform the same function as triclosan or bisguanide antimicrobials, as taught by Ong, in a polyacrylate coating material on a medical device inserted into a human patient.

Ans. 6–7.

Appellant argues that Nishtala teaches away from the claimed invention because “while Nishtala may teach the inclusion of various non-metal salt antimicrobial agents, the polymeric coatings of Nishtala require that at least one of the components be ‘a colloid comprising a salt or oxide of one or more oligodynamic metals.’” App. Br. 11. Appellant contends that Nishtala’s teaching that a metal salt or oxide is required is contrary to the limitation of claims 9, 10, and 18–22 requiring “an antimicrobial agent . . . excluding metal salts.” We are not persuaded.

The Examiner relied upon Nishtala for its teaching that the antimicrobials recited in claims 9, 10, and 18–22 were “known as equivalents which perform the same function as triclosan or biguanide antimicrobials.” Ans. 6–7. Appellant’s argument that Nishtala requires metal salts is not persuasive because it does not establish that Nishtala’s teaching of known equivalence among antimicrobials was incorrect.



In addition, it is not clear that Nishtala does, in fact, require a metal salt or oxide. Appellant argues that “Nishtala teaches a polymeric coating ‘that includes at least one polymer and a colloid comprising a salt or oxide of one or more oligodynamic metals, wherein the salt or oxide of one or more oligodynamic metals inhibits microbial adherence of one or more organisms to the composition.’” App. Br. 11. However, even assuming that Nishtala does require a metal salt or oxide, the claims at issue exclude only the use of metal salts. They do not exclude the use of metal oxides. The use of Nishtala’s equivalent antimicrobials together with a metal oxide would thus not be inconsistent with language of claims 9, 10, and 18–22.

Accordingly, we affirm the Examiner’s rejection of claims 9, 10, and 18–22 over the combination of Krongauz, Elton, Ong and Nishtala.

#### SUMMARY

For these reasons and those set forth in the Examiner’s Answer, and the Final Office Action, the Examiner’s final decision to reject claims 1, 3, 5, 7, 9, 10, and 12–23 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

#### AFFIRMED